REMARKS/ARGUMENTS

Claims 1-5, 9-14, and 61-72 were pending in the Application. Claims 1-5, 9-14, and 61-72 are canceled by the present amendment, without prejudice to further prosecution in a related application. New claims 73-83 are added. The previous claims are canceled and the new claims are added to expedite prosecution of certain embodiments, and not for reasons related to patentability.

New claims 73-83 are directed to pharmaceutical formulations comprising FRIL family member molecules. Support for claims to pharmaceutical formulations comprising FRIL family member molecules can be found in the originally filed claims, *e.g.*, claims 9-14, as well as the specification, *e.g.*, page 4, line 24 through page 5, line 12.

Support for the limitation that FRIL family member molecules bind normally glycosylated FLT3 receptor can be found in the originally filed claims, *e.g.*, claim 57, as well as the specification, *e.g.*, page 24, line 26 through page 25, line 21.

Support for the limitation that FRIL family member molecules can preserve progenitor cells can be found in the originally filed claims, *e.g.*, claims 1, 42 and 49, as well as the specification, *e.g.*, page 22, line 22 through page 24, line 25; page 27, line 21 through page 28, line 13; page 67, line 23 through page 71, line 14; and page 86, line 1 through page 100, line 17.

Support for FRIL family member molecules encoded by nucleic acids that hybridize under stringent conditions to sequences complementary to SEQ ID NO: 1, SEQ ID NO: 5 or SEQ ID NO: 7 can be found in the specification, *e.g.*, page 21, line 16 through page 22, line 21.

Support for FRIL family member molecules having at least 95% amino acid sequence identity to SEQ ID NO: 2, SEQ ID NO: 6, or SEQ ID NO: 8 can be found in the specification, *e.g.*, page 19, line 27 through page 20, line 13.

Support for the limitation that FRIL family member molecules can reduce or alleviate the progenitor cell depleting activity of certain therapeutic treatments can be found in the originally filed claims, *e.g.*, claims 10 and 15, as well as the specification, *e.g.*, page 37, line 4 through page 38, line 29.

Support for the limitation that the subject of treatment can be a human undergoing treatment for cancer can be found in the originally filed claims, *e.g.*, claims 11-12, 16-17, 46 and 50-51, as well as the specification, *e.g.*, page 38, lines 1-29.

Support for the limitation that the therapeutic treatment having progenitor cell depleting activity can be radiotherapy, chemotherapy, or a combination of radiotherapy and chemotherapy can be found in the originally filed claims, *e.g.*, claims 13, 18 and 47, as well as the specification, *e.g.*, page 38, lines 1-29.

Support for the limitation that the chemotherapy can include administration of cytarabine, doxorubicin or 5-fluorouracil can be found in the originally filed claims, *e.g.*, claims 14, 19 and 48, as well as the specification, *e.g.*, page 38, lines 11-14.

Support for the limitations that the pharmaceutical carrier can be suitable for parenteral administration, and that the parenteral administration can include intravenous, intra-arterial, subcutaneous, intramuscular, intraperitoneal or intra-marrow administration, can be found in the specification, *e.g.*, page 39, lines 1-23.

Support for the limitations that the FRIL family member molecule can comprise the amino acid sequences of SEQ ID NO: 2, SEQ ID NO:6 or SEQ ID NO: 8 can be found in the specification, *e.g.*, page 28, line 16 through page 29, line 7.

In light of the foregoing, Applicants submit that no new matter is added by the addition of the new claims.

Applicants note that the new claims are all directed to pharmaceutical formulations comprising a FRIL family member molecule. Applicants believe that, prior to the present invention, there was no known or obvious *therapeutic* or *pharmaceutical* use for any FRIL family member molecule. Rather, Applicants' discovery of the utility of these molecules as FLT3 receptor interacting ligands, and their ability to preserve progenitor cells and maintain them in a state of quiescence even when subjected to cell proliferation and differentiation signals, provided the first motivation in the art to use these molecules as therapeutics, pharmaceuticals or reagents for the various purposes described in the specification. Therefore, Applicants submit, the present claims directed to pharmaceutical formulations are both novel and non-obvious over prior art reports which merely describe the existence of various lectins and their carbohydrate-binding specificities (*e.g.*, Gowda *et al.* (1994)).

The previously pending claims being canceled, the previous rejections are rendered moot. Nonetheless, to expedite prosecution of the claims, the previous grounds for rejection are discussed below in the context of the new claims.

Rejections Under 35 U.S.C.§ 112, First Paragraph

Claims 1-5, 9-14, and 61-72 were rejected under 35 U.S.C. § 112, first paragraph, for purportedly failing to provide an enabling disclosure. As noted above, the cancellation of these claims renders the rejections moot.

With respect to the new claims, however, Applicants submit that the full scope of the claims is fully enabled by the specification and knowledge in the art. Each of the claims includes both structural and functional limitations, including references to specifically disclosed sequences, which allow the skilled artisan to vary the disclosed sequences within defined structural limits, and to test for the required functional characteristics by methods which are both disclosed in the specification and known in the art. Therefore, Applicants respectfully submit that, in light of the disclosure in the specification, as filed, and the level of routine skill in the art, no more than routine experimentation would be required to make and use the full scope of the claimed invention.

Accordingly, Applicants respectfully submit that the prior rejections under 35 U.S.C. § 112, first paragraph, do not apply to the present claims.

Claims 1-5, 9-14, and 61-72 also were rejected under 35 U.S.C. § 112, first paragraph, as purportedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that, at the time the application was filed, the inventors had possession of the claimed invention. Again, the cancellation of these claims renders the rejections moot.

With respect to the new claims, however, Applicants submit that the full scope of the claims is fully described in the specification. Specifically, as described in detail above, there is literal support in the specification, including the originally filed claims, for each and every claim limitation. This literal support includes experimental evidence demonstrating the identification, cloning, sequencing, site-specific mutagenesis, and functional characterization of exemplary

members of the FRIL family of progenitor cell preservation factors. Therefore, the specification does, in fact, reasonably convey that the inventors were in possession of the presently claimed inventions at the time of filing.

Accordingly, Applicants respectfully submit that the prior rejections under 35 U.S.C. § 112, first paragraph, do not apply to the present claims.

Claim 72 was rejected under 35 U.S.C. § 112, first paragraph, as purportedly containing new matter. As claim 72 has been canceled, this ground for rejection has been rendered moot.

Rejections Under 35 U.S.C.§ 102(b)

Claims 1-5, 9-14, and 61-72 were rejected under 35 U.S.C. § 102(b) as purportedly being anticipated by Moore *et al.* (1997), *Blood* 90:428A ("Moore"). The cancellation of these claims renders the rejections moot.

With respect to the new claims, however, Applicants submit that this reference similarly fails to anticipate the claimed invention.

Specifically, Moore describes a partially purified lectin from red kidney bean extract that was identified by its ability to specifically stimulate the proliferation of 3T3 fibroblasts transfected with the tyrosine kinase receptor FLT3. A fraction containing this lectin was reported to maintain a small population of cord blood cells in a CD34-expressing state.

However, nowhere does Moore teach the amino acid sequence of a FRIL family member isolated from red kidney beans or any other species. Nor does Moore teach the sequence of a nucleic acid molecule encoding any member of the FRIL family of progenitor cell preservation factors. The Federal Circuit has stated that an anticipating reference must enable that which it is asserted to anticipate (see, *e.g.*, Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F. 3d, 131, 1354 (Fed. Cir. 2003)). Failing to disclose the nucleotide or amino acid sequence of any FRIL family member molecules, Moore cannot anticipate the present claims, which are structurally limited by such sequences.

Thus, Applicants submit that the prior rejection under 35 U.S.C. § 102(b) over Moore does not apply to the present claims.

CONCLUSION

Claims 1-5, 9-14, and 61-72 were pending in the Application. Claims 1-5, 9-14, and 61-72 are canceled by the present amendment, without prejudice to further prosecution in a related application. New claims 73-83 are added. Applicants submit that no new matter has been added by the new claims.

This Amendment and Response is being filed as a Submission with a Request for Continued Examination under 37 CFR 1.114 and the required fee under 37 CFR 1.17(e). Applicants believe that no additional fees are required. However, in the even that any additional fees are required to maintain the pendency of this application, the Commissioner is hereby authorized to charge any such fees, or to credit any overpayments, to Attorney Deposit Account No. 08-0219.

Applicants respectfully request that the Examiner reconsider the application and claims in light of the foregoing amendments and remarks. Applicants believe that the claims, as newly presented, are in condition for allowance. If the Examiner believes that a telephone interview would be help expedite the successful prosecution of the claims, the undersigned attorney would be grateful for the opportunity to discuss any outstanding issues.

Respectfully submitted,
HALE AND DORR LLP

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Michael J. Twomey
Reg. No. 38,349
Attorney for Applicants

Hale and Dorr, LLP
60 State Street
Boston, MA 02109
Tel: (617) 526-6190
Fax: (617) 526-5000